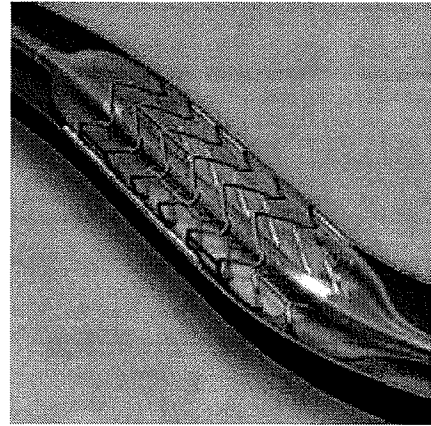


Your Treatment Options *(continued)*

Step 2:

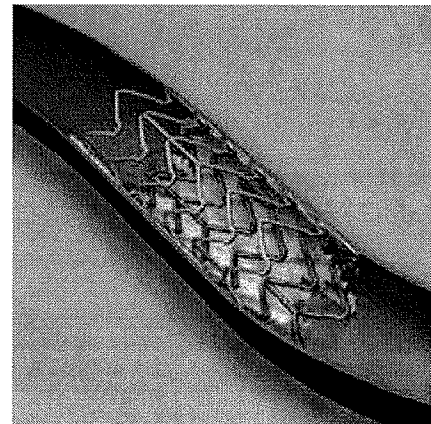
The stent expands against the vessel wall as the balloon is inflated.



Step 2

Step 3:

Once the balloon has been deflated and the catheter is withdrawn, the stent stays in place permanently, holding the blood vessel open and improving blood flow.



Step 3

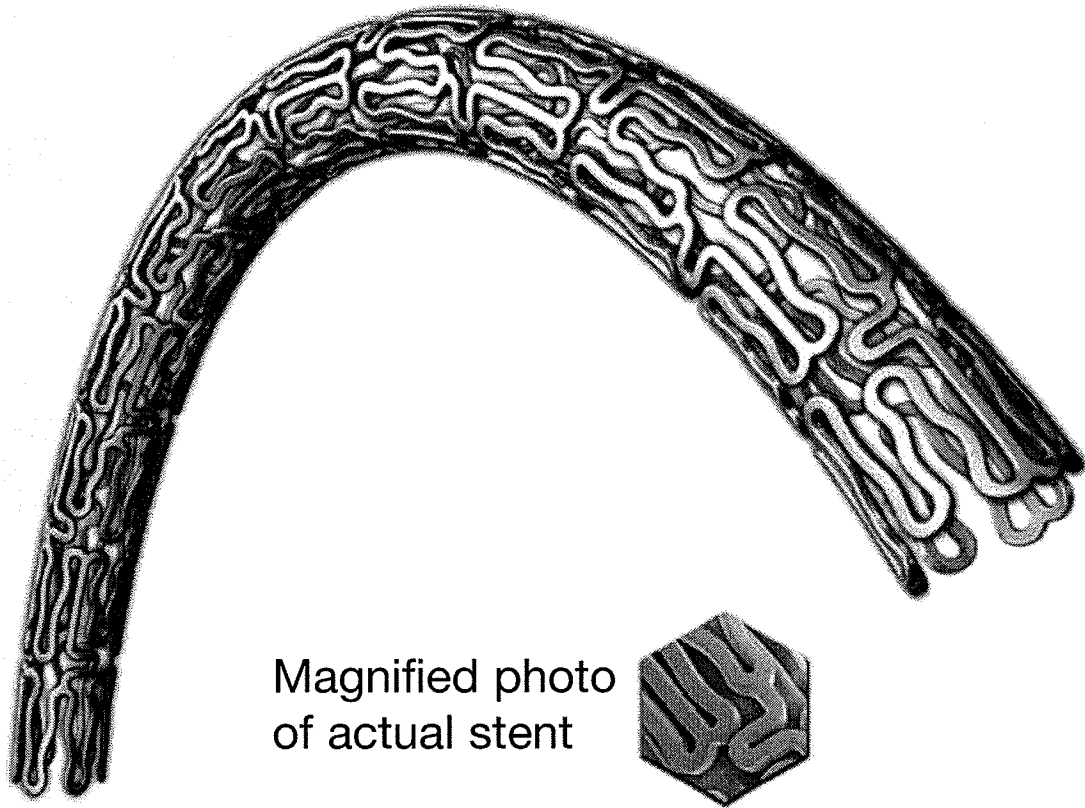
Coronary artery stents are less invasive than bypass surgery. Stenting involves a shorter hospital stay — usually one to three days — and faster recovery than surgery. However, restenosis can also occur in some patients who receive stents (in-stent restenosis) due to the build-up of scar tissue within the stent leading to narrowing of the stent lumen.

Drug Eluting Stents (DES)

To help prevent restenosis, “drug-eluting” stents have been developed. These stents provide the same structural support as uncoated stents, but they also have a drug coated on them. The drug is released over time, helping to prevent restenosis by limiting the overgrowth of normal tissue within the stent.

PROMUS Everolimus-Eluting Coronary Stent System

The illustration shown is an artist's rendition of Boston Scientific's drug eluting stent, the PROMUS.



The PROMUS Everolimus-Eluting Coronary Stent System (PROMUS EECSS or PROMUS Stent System) is a private label XIENCE™ V Everolimus Eluting Coronary Stent System manufactured by Abbott and distributed by Boston Scientific Corporation.

PROMUS Everolimus-Eluting Coronary Stent System *(continued)*

The PROMUS stent is designed to prevent re-narrowing within the stent (in-stent restenosis). It consists of a medical grade cobalt chromium stent with a thin coating of a drug called everolimus on its surface. This stent is based on the design of the clinically proven MULTI-LINK VISION® stent and provides mechanical support to the artery while everolimus is slowly released into the artery wall around the stent from a thin polymer (a type of plastic) coating. The polymer coating helps control the release of everolimus into the arterial wall. The polymer used on the PROMUS stent has a long history of being used in medical products in contact with blood. The release of everolimus is intended to limit the overgrowth of tissue within the coronary stent.

PROMUS Everolimus-Eluting Coronary Stent System *(continued)*

Contraindications:

- If you have a known hypersensitivity (allergy) or contraindication to everolimus or structurally-related compounds cobalt, chromium, nickel, tungsten, acrylic, and fluoropolymers
- If you cannot take aspirin or blood-thinning medications (also called antiplatelet or anticoagulant therapy)
- If your physician decides that the coronary artery blockage will not allow complete inflation of the angioplasty balloon or proper placement of the stent

Potential Adverse Events Associated with the PROMUS Stent

The risk of using the PROMUS stent is similar to those that are associated with standard stent procedures. If the stent clots, you may need another angioplasty procedure. It may also lead to a heart attack, the need for urgent bypass surgery, or death. Even with successful stent implants, there is a chance of re-narrowing of your coronary artery. This may require further treatments, such as repeat angioplasty and/or bypass surgery, to reopen the artery and to increase blood flow to the heart. The risks from using balloon catheters after stent implants are similar to the risks that may occur during the initial stent implant. These may be serious enough to require surgery or cause death.

Other risks from these devices are the same as treatment procedures for a narrowed coronary artery. Some problems associated with standard balloon angioplasty and stenting include, but are not limited to:

Potential Adverse Events Associated with the PROMUS Stent *(continued)*

Common Risks

- Bruise or bleeding at the catheter insertion site in the groin or arm
- Pain at the catheter insertion site
- Irregular heartbeats
- Chest pains during and after the procedure
- Spasm of the coronary artery
- Decreased or increased blood pressure

Rare Risks

- Tearing, puncture, or rupture of the coronary artery
- Air, pieces of devices, or fragments of clots blocking the coronary or peripheral arteries
- Complete blockage of the coronary artery, which may require a repeat procedure to reopen the coronary artery
- Compression of the heart due to accumulation of blood around the heart
- Re-narrowing of the coronary artery
- Heart attack

Potential Adverse Events Associated with the PROMUS Stent *(continued)*

- Damage to the stent or injury to the coronary artery, requiring emergency heart surgery
- Bleeding, requiring transfusion or surgery
- Allergic reaction (may include X-ray dye, cobalt, chromium, nickel, tungsten, everolimus, acrylic, and fluoropolymer)
- Infection
- Nerve injury
- Kidneys fail to function normally
- Aneurysm (weakening of a portion of the wall of a blood vessel)
- Shock
- Stroke
- Death

Potential Adverse Events Associated with the PROMUS Stent *(continued)*

Potential adverse events related to taking everolimus daily by mouth (based on long-term everolimus drug studies in organ transplant patients) may include:

Acne, decreased red or white blood cells, blood clotting abnormalities, diarrhea, water retention in the body, destruction of red blood cells, increased blood cholesterol, increased fat in the blood, increased blood pressure, decreased functioning of sexual organs in men, infections, liver function test abnormality, white blood cell abnormalities, nausea, pain, rash, destruction of the kidney tubules, surgical wound complication, decreased platelet cell count, blood clot in the vein, or vomiting.

Exposure to drug and polymer on the PROMUS stent is directly related to the number and lengths of the stents implanted. The use of multiple PROMUS stents will result in you receiving larger amounts of drug and polymer. It should be noted that a kidney transplant patient usually receives a daily dose of the drug everolimus by mouth that is about seven times more than the maximum dose of the drug contained on one PROMUS stent.

Potential Adverse Events Associated with the PROMUS Stent *(continued)*

Everolimus, when given by mouth daily to organ transplant patients, may interact with other drugs or substances. Please tell your physician about any medications you are taking.

The SPIRIT Family of Clinical Trials

The PROMUS Everolimus-Eluting Coronary Stent System (PROMUS EECSS or PROMUS Stent System) is a private label XIENCE™ V Everolimus Eluting Coronary Stent System manufactured by Abbott and distributed by Boston Scientific Corporation. There have been three clinical trials thus far that together have shown the safety and effectiveness of the XIENCE V drug eluting stent in patients with coronary artery disease. A short description of these trials, known as the XIENCE V SPIRIT Family of Trials, is detailed below.

SPIRIT FIRST

SPIRIT FIRST was the first clinical trial. This study had 60 patients and was performed outside the United States. The purpose of the study was to compare the XIENCE V stent that is coated with a drug to that of an approved metallic stent that is not coated with a drug. There were 28 patients who received the XIENCE V stent and 32 patients who received the metallic stent (patients who received the metallic stent are also known as the “control” group).

The SPIRIT Family of Clinical Trials *(continued)*

After six months, the XIENCE V stent was significantly better than the metallic stent at reducing the re-narrowing of the artery where the stent was placed. After three years, patients who had received the XIENCE V stent had fewer major adverse cardiac events (15.4%) compared to patients who received the metallic stent (25.0%).

SPIRIT II

The SPIRIT II clinical trial was the second study of the XIENCE V stent. The purpose of the study was to compare the XIENCE V stent to an approved drug eluting stent, called TAXUS®. The SPIRIT II study was conducted outside of the United States.

After six months, the XIENCE V stent was significantly better than the TAXUS stent at reducing the re-narrowing of the artery where the stent was placed. At two years, patients who had received the XIENCE V stent had a rate of major adverse cardiac events (6.6%) that was comparable to the TAXUS stent (11.0%).

The SPIRIT Family of Clinical Trials *(continued)*

SPIRIT III

SPIRIT III was the third clinical study of the XIENCE V stent. This was a much bigger study than either the SPIRIT FIRST or SPIRIT II studies, and was conducted in the United States. In one part of this study, 1002 patients were given either the XIENCE V stent or the TAXUS stent. There were 669 patients who received the XIENCE V stent and 333 patients who received the TAXUS stent.

After eight months, the XIENCE V stent was significantly better than the TAXUS stent at reducing the re-narrowing of the artery where the stent was placed. At one year, patients who had received the XIENCE V stent had a rate of major adverse cardiac events (6.0%) that was comparable to the TAXUS stent (10.3%).

For patients treated with the XIENCE V stent in ways not studied in these clinical trials, clinical results may vary. Very long-term (beyond 24 months) risks and benefits associated with the XIENCE V stent are currently unknown.

Your Drug Eluting Stent Procedure

How Do I Prepare for My Procedure?

In the days prior to your treatment, make sure you:

- Take all of your prescribed medicines
- Tell your doctor if you are taking any other medication
- Tell your doctor if, for any reason, you cannot take aspirin and/or Plavix®
- Make sure your doctor knows about any allergies you have
- Refrain from eating and drinking after midnight on the night before your treatment
- Follow all instructions given to you by your doctor or nurse

You may be given a mild sedative to help you relax, but you will not be put to sleep. There are two reasons for this. First, most people find they experience little to no discomfort from the procedure. Secondly, your doctor may need to ask you to take a deep breath while X-rays are being taken, to improve the quality of the pictures.

Your Drug Eluting Stent Procedure *(continued)*

The procedure usually lasts about 90 minutes, during which time your doctor will ask you to remain very still. For the most part, you will be comfortable, but you may feel some pressure or chest pain when the balloon is inflated. This is normal and will quickly fade when the balloon is deflated.

Your Drug Eluting Stent Placement Procedure

Your procedure will be performed in a cardiac catheterization laboratory (cath lab). You will lie on the X-ray table, and an X-ray camera will move over your chest during the procedure. The staff will monitor your heart by attaching several small, sticky patches to your chest and using a specialized ECG recorder and monitor.

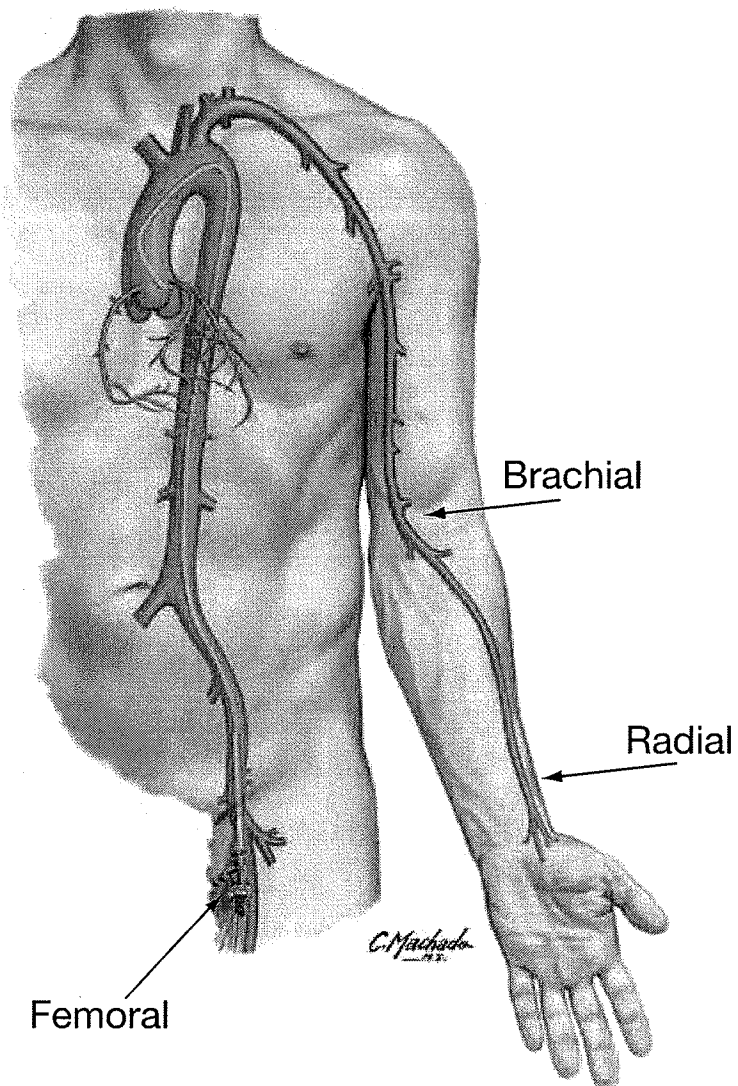
The groin is the most common site for catheter introduction and requires a very small skin incision to be made on the inside of your upper thigh. The area will be shaved and cleaned with an antiseptic,

Your Drug Eluting Stent Procedure *(continued)*

and you will be given a local anesthetic to numb the area. This incision will allow an introducer sheath (short tube) to be inserted into your femoral artery (the main artery of the thigh, supplying blood to the leg). Your doctor will then insert a guiding catheter (long, flexible tube) into the introducer sheath and advance it to where the coronary arteries branch off to the heart. A guide wire is then advanced through the guiding catheter to the narrowing in the coronary artery. This helps carry all the necessary devices required during the stenting procedure.

Additional options for catheter introduction are the arm/brachial approach (incision is made on the inside of your elbow) and the wrist/radial approach (incision is made on the inside of your wrist).

Your Drug Eluting Stent Procedure *(continued)*



**Blood vessel access for heart catheterization
through the femoral, radial or brachial artery**

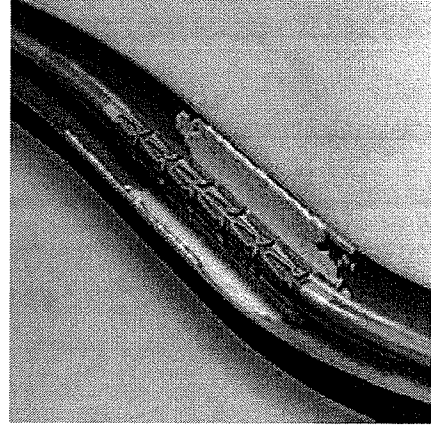
Your Drug Eluting Stent Procedure *(continued)*

After the catheters are inserted, your doctor will inject a contrast dye through the guiding catheter into your artery to view the narrowing. Your doctor will watch the injection on an X-ray monitor, much like a TV screen. While these X-rays are being taken, your doctor may ask you to take a deep breath and hold it for a few seconds. You may also be asked to cough after the X-ray picture is completed to help speed the removal of the contrast dye from the arteries.

Using the guiding catheter, a balloon catheter is positioned in the narrowing in the coronary artery and the balloon is then inflated. This compresses the plaque and widens the coronary artery. This procedure is called pre-dilatation.

Step 1:

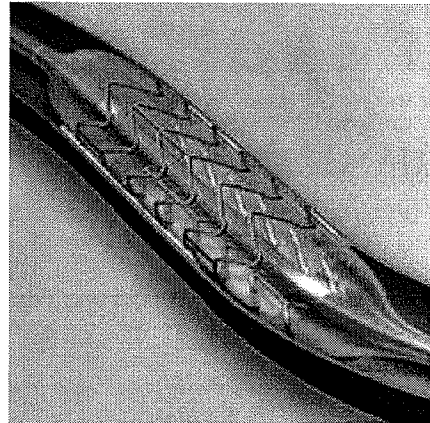
The stent mounted on a balloon catheter is delivered to the narrowing in the coronary artery by a delivery catheter.



Step 1

Step 2:

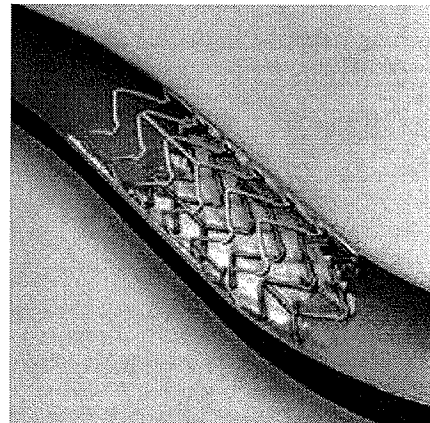
The balloon is then inflated and this expands the stent, pressing it against the coronary artery wall. Your doctor may choose to expand the stent further by using another balloon so that the stent can make better contact with the artery wall. This is known as post-dilatation.



Step 2

Step 3:

Once in place, the PROMUS stent will remain as a permanent implant in your coronary artery.



Step 3

Your Drug Eluting Stent Procedure *(continued)*

Immediately after Procedure

You will be asked to lie flat for four to six hours following the procedure and to not bend your leg or arm, depending on which area your doctor used to insert the catheters. Pressure will also be placed on the area.

A vascular closure device may be used to seal the incision site in your groin or arm. You will be allowed to get up and walk around sooner if this type of device is used. Your hospital stay may range from one to three days.

Medications will be prescribed for you before and after stent placement. Antiplatelet medications such as aspirin and Plavix® are the most commonly prescribed. They help prevent a blood clot (thrombus) from forming and blocking the stent lumen. Your doctor or nurse will give you instructions about your medications before you leave the hospital.

Your Drug Eluting Stent Procedure *(continued)*

CAUTION: If you have any chest pain, or discomfort or bleeding from your incision site, call your doctor immediately. If your doctor is unavailable, call for an ambulance to take you to the nearest hospital emergency room.

Take All Medications as Instructed

After you leave the hospital, your cardiologist will instruct you to take a daily dose of aspirin and another antiplatelet drug such as Plavix®. Your doctor will tell you how long you should continue taking the antiplatelet drugs. It is very important that you take these medications exactly as your doctor instructs you:

- Follow your medication schedule exactly to avoid possible complications after you receive your stent. Do not miss any doses.
- Call your doctor if you cannot keep taking your medications because of side effects such as rash, bleeding, or upset stomach.

Your Drug Eluting Stent Procedure *(continued)*

- **CAUTION:** Do not stop taking your prescribed medications unless you are instructed to do so by the doctor who performed your stent procedure.
- **CAUTION:** Notify your cardiologist or family doctor if you are scheduled to see the dentist while on antiplatelet medication. Your doctor may prescribe antibiotics to avoid the potential of an infection. You should review with your doctor any recommendations from your dentist to stop your prescribed medications.
- **CAUTION:** Before undergoing implantation of a drug eluting stent, if you plan to have any type of surgery, which may require you to stop taking antiplatelet medications, you and your cardiologist should discuss whether or not placement of a drug eluting stent is the right treatment choice for you.

If surgery or dental work, which would require you to stop taking antiplatelet medications, is recommended after you've received the stent, you and your doctors should carefully consider the risks and benefits of this surgery or dental work versus the possible risks from early discontinuation of these medications.

Your Drug Eluting Stent Procedure *(continued)*

If you do require discontinuation of antiplatelet medications because of significant bleeding, your cardiologist will carefully monitor you for possible complications. Once your condition has stabilized, your cardiologist may put you back on these medications.

Follow-Up Care

You will be discharged to the care of your cardiologist or family doctor. You should be able to return to your normal activities soon.

CAUTION: Notify your doctor immediately if you experience chest pain (angina), or notice any changes such as more severe or frequent chest discomfort, especially in the first month after a procedure. These symptoms may indicate a re-narrowing in your coronary arteries.

Your Drug Eluting Stent Procedure *(continued)*

Your doctor will ask you to return for follow-up visits. The first visit is usually two to four weeks after your stent is implanted, with follow-up visits every six months for the first year. Be sure to keep all appointments for follow-up care, including blood tests.

Keep Your ID Card Handy

CAUTION: Show your identification card if you report to an emergency room. This card identifies you as a patient who has had a stent implanted.

If you require a magnetic resonance imaging (MRI) scan, tell your doctor or MRI technician that you have a stent implant. Test results indicate that patients with single or overlapped PROMUS stents can undergo MRI scans safely under the following conditions:

- Static magnetic field of 1.5 or 3 Tesla
- Spatial gradient field of 720 Gauss/cm or less

Your Drug Eluting Stent Procedure *(continued)*

- Maximum whole-body-averaged specific absorption rate (SAR) of 2.0 W/kg (normal operating mode) for 15 minutes of scanning or less

The stent(s) should not migrate in this MRI environment, and MRI may be performed immediately following the implantation of the PROMUS stent(s). Prior to undergoing an MRI scan, inform your doctor that you have a PROMUS Everolimus-Eluting Coronary Stent.

Preventing Coronary Artery Disease

Coronary artery disease can be treated effectively, but it has no cure. You can help to prevent your coronary artery disease from progressing by carefully following your doctor's advice. Your doctor may prescribe medications to help control your blood pressure, diabetes, and/or high cholesterol. Your doctor may also recommend some lifestyle changes. Among the healthy choices you can make:

Stop smoking. If you smoke, quitting is the single most important thing you can do to lower your risk of coronary artery disease. Chemicals in cigarette smoke may make it easier for plaque to build up on your artery walls. And smoking increases your heart rate and blood pressure, raising your risk of heart attack and stroke. If you're ready to quit, ask your doctor for advice — he or she can recommend smoking cessation aids to help you quit.

Preventing Coronary Artery Disease *(continued)*

Increase your activity and eat a healthy diet. A sedentary lifestyle increases your risk. Your doctor can recommend an activity program tailored for your situation. Regular exercise can help you lower your blood pressure and blood cholesterol and reach a healthy weight. It can also help you manage the daily stresses of modern life more easily. Choose a healthy diet. A diet low in saturated fats and cholesterol and rich in lean protein, fresh fruits, vegetables and whole grains, can help you achieve a healthy weight and control your blood pressure, and cholesterol levels.

Manage your stress. Stress is an inescapable aspect of modern day living, but you can help lessen its negative health effects by practicing the “relaxation response.” Research has shown that relaxation techniques can improve your ability to cope with stressful events while decreasing your heart rate, blood pressure, and stress hormone levels.

Frequently Asked Questions

How long will the stent stay in my body?

Stents are designed to stay in your body permanently.

What are the restrictions or cautions after I've received a stent?

If you require magnetic resonance imaging (MRI), tell your doctor or MRI technician that you have an implanted stent.

When can I resume my regular activities?

Your doctor will advise you. Many patients can return to work and follow their normal routine about a week after their stent procedure.

Will my stent set off the metal detector at airport security checkpoints?

No, your stent implant will not trigger alarms at security checkpoints.

Frequently Asked Questions

(continued)

Will I be able to feel the stent inside me?

No, you will not be able to feel the stent once it has been implanted in your artery.

Could I have recurring symptoms?

Yes, it is possible that you will experience symptoms again, either due to a new blockage in the region treated with the stent or a blockage at another place in your coronary arteries. Your doctor will monitor your progress.

How can I help prevent a recurrence of symptoms?

While there is no sure way to prevent a recurrence of symptoms, you can reduce the risk through exercise, not smoking, and eating a healthy diet. Your doctor can advise you about lifestyle changes.

Definition of Medical Terms

Angina: Chest pain caused by inadequate supply of blood to the heart.

Angioplasty (also referred to as PTCA): A minimally invasive procedure in which a balloon dilatation catheter is passed through to the blocked area of an artery. Once inflated the catheter compresses the plaque against the blood vessel wall and enlarges the vessel opening. An angioplasty can also be performed with placement of a stent.

Anticoagulant: A medication to prevent or slow the clotting of blood.

Antiplatelet: A substance to reduce clumping of platelets in the blood. An antiplatelet medicine helps thin the blood to prevent clot formation.

Atherosclerosis: A disease that causes narrowing or blockage of arteries caused by a build-up of fat (cholesterol) within the artery wall. The build-up is sometimes referred to as “plaque.”

Definition of Medical Terms

(continued)

Cardiac Catheterization Laboratory (Cath Lab): A sterile X-ray theater in which heart catheterization is performed.

Catheter: A thin, hollow, flexible tube used to access the coronary arteries during an angiogram or during an angioplasty procedure. This catheter can be used to inject medication, fluids, or contrast dye during your procedure. Catheter is also used to describe the device used to deliver the balloon or stent during an angioplasty procedure.

Coronary Angiography (or Heart Catheterization or Cardiac Cath): A test in which contrast dye is injected to create images of the coronary arteries and the chamber of the heart. This allows the doctor to see the extent of the disease in the coronary arteries and make a decision on how to best treat the blockages.

Coronary Arteries: The blood vessels that carry oxygenated blood from the aorta to the heart muscle. There are four major coronary arteries: the left main,

Definition of Medical Terms

(continued)

the right coronary artery, the left anterior descending, and the circumflex.

Coronary Artery Bypass Graft Surgery (CABG): Open-heart surgery to treat CAD.

Coronary Artery Disease (CAD): The formation of blockages or atherosclerotic plaques within coronary arteries that result in restricted blood flow to the heart muscle.

Electrocardiogram (ECG/EKG): A test that records changes in the electrical activity of the heart. An ECG/EKG may show whether parts of the heart muscle are damaged due to decreased blood flow to the heart muscle.

Femoral Artery: The main artery of the thigh, supplying blood to the leg.

Definition of Medical Terms

(continued)

Fluoroscope: An X-ray device that creates an image of the body that can be viewed on a TV monitor. This permits the doctor to obtain real-time images of the internal structures of a patient.

In-stent Restenosis: Recurrent blockage or narrowing of a previously stented vessel.

Local Anesthetic: A substance used to numb the area to which it is applied.

Lumen: The inner channel or cavity of a vessel or tube. In a blood vessel, it is the opening through which blood flows.

Myocardial Infarction (MI): Also called a heart attack. Permanent damage of an area of the heart tissue, due to interruption in the blood flow to the heart muscle (myocardium).

Definition of Medical Terms

(continued)

Magnetic Resonance Imaging (MRI): A non-invasive diagnostic procedure used to obtain images of internal body structures through the use of magnets and radio waves.

Percutaneous: Performed through the skin.

Plaque: An accumulation or build-up of fatty deposits, calcium, white blood cells, and other substances in the wall of an artery that results in narrowing of the vessel lumen.

Restenosis: A recurring blockage caused by the excessive growth of scar tissue inside the artery or stent, following an interventional procedure such as angioplasty.

Stent: A metallic mesh tube that is implanted into an artery during an angioplasty, providing a scaffold to help hold the artery open, ensuring blood flow to the heart muscle.

Definition of Medical Terms

(continued)

Transluminal: Through the inside opening of a vessel or artery.

Boston Scientific

Distributed By:
Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537 USA
USA Customer Service:
1-888-272-1001
www.bostonscientific.com/promus

Manufactured By:
Abbott Vascular
Santa Clara, CA
95054-2807 USA

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EL2063086 (9/25/03) (LT2923082)

A1164